UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,324	06/28/2004	Francesco Paolini	07552.0031	8942

22852 7590 07/13/2009

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
07/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte FRANCESCO PAOLINI, FRANCESCO FONTANAZZI, and MASSIMO ZACCARELLI

Appeal 2009-002683
Application 10/500,324
Technology Center 3700

Decided:[1] July 10, 2009

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and STEPHEN WALSH, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method and apparatus for extracorporeal blood treatment. The Examiner has

---

[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The Specification discloses control equipment and control methods that regulate temperature in extracorporeal blood circuits.

Claims 26 and 28-50 are on appeal. Claims 26 and 45 are representative and read as follows:

Claim 26: An apparatus for control of an extracorporeal blood circuit connected to a blood purification machine, said extracorporeal blood circuit comprising

an access branch, having one end connected to at least one blood treatment element inlet and another end connected to a patient,

a return branch, having one end connected to an outlet of said at least one blood treatment element and another end connected to a patient;

said apparatus comprising:

a sensor located in the access branch upstream of all blood treatment elements for measuring a first temperature of blood leaving a patient along the access branch upstream of said at least one blood treatment element;

a temperature regulating device for regulating said blood temperature in the extracorporeal blood circuit, said temperature regulating device comprising a line conveying a fluid, said line being coupled to a portion of the return branch downstream of all blood treatment elements to form a heat exchanger directly before blood is returned to the patient;

and a control unit connected to said temperature regulating device for controlling the blood temperature by controlling the temperature of the fluid conveyed in said line as a function of said first temperature and of a reference temperature.

Claim 45: [A control method for an extracorporeal blood circuit for the circulation of blood in a blood purification machine, the extracorporeal blood circuit comprising

an access branch and a return branch, said access branch and return branch being connected to at least one blood treatment element,

the control method comprising the steps of:

connecting the access branch to a patient and to an inlet of said blood treatment element;

connecting the return branch to the patient and to an outlet of said blood treatment element;

measuring a first temperature of the blood in correspondence of said access branch upstream of all blood treatment elements; and

regulating a blood temperature in the extracorporeal blood circuit as a function of the first temperature and of a reference temperature, the blood temperature in the extracorporeal blood circuit being regulated along a portion of the return branch and downstream of all blood treatment elements, directly before blood is returned to the patient,

wherein a fluid is conveyed along said temperature regulating device, said fluid having a fluid temperature that varies within a specified range about 37° C,]

wherein blood is conveyed along the extracorporeal blood circuit by means of a pump, a state of operation of the pump being detected, the fluid temperature being regulated as a function of the first temperature and of the reference temperature, and the fluid temperature being kept equal to the reference temperature when the pump is not in operation.

OBVIOUSNESS

Issue

The Examiner has rejected claims 26 and 28-50 under 35 U.S.C. § 103(a) as being obvious in view of Weitzel,[2] Polaschegg,[3] and Derek.[4] Claim 45 was argued separately. Claims 28-44 and 46-50 have not been argued separately and therefore stand or fall with claim 26. 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner finds that Weitzel discloses an extracorporeal blood circuit apparatus that comprises an access branch, a return branch, and a

---

[2] Weitzel et al., US 6,561,997 B1, May 13, 2003
[3] Polaschegg, US 4,894,164, Jan. 16, 1990
[4] Derek et al., US 6,582,387, June 24, 2003

blood treatment element, and that allows for precise control over fluid temperature in the circuit (Ans. 4). The Examiner also finds that Weitzel discloses a heat exchanger that "functions to keep the blood at a physiological temperature" (*id.*).

The Examiner finds that Polaschegg discloses "a blood treatment apparatus comprising a temperature sensor 206 located in the access branch 220 and upstream of all blood treatment devices" (*id.*). The Examiner concludes that "it would have been obvious to one skilled in the art … to combine the apparatus of Weitzel et al. with the temperature sensor placement of Polaschegg in order to measure the true temperature of blood leaving the body for use as a reference temperature for controlling the heat exchanger 8" (*id.* at 4-5).

The Examiner finds that Derek "discloses a blood treatment apparatus wherein a heat exchanger may be placed within the return tube …, which is downstream of all blood treatment elements" (*id.*). The Examiner concludes that "it would have been obvious to one skilled in the art … to modify the blood treatment apparatus of Weitzel et al. with the heat exchanger placement of Derek et al. in order to minimize temperature change before blood reenters the body" (*id.*).

Appellants contend that the Examiner erred in finding that the cited references suggest a heat exchanger downstream of all blood treatment elements, and directly before blood is returned to the patient, that regulates the blood temperature as a function of temperature in the access branch and a reference temperature (Appeal Br. 17). Appellants also contend that the Examiner erred in finding that one of skill in the art would have been

motivated to combine the cited references to arrive at the invention of claim 26 (*id.* at 21).

The issues presented are: Does the evidence of record support the Examiner's findings that (i) the cited references suggest a heat exchanger downstream of all blood treatment elements and directly before blood is returned to the patient that regulates the blood temperature as a function of temperature in the access branch and a reference temperature and (ii) that one of skill in the art would have been motivated to combine the cited references to arrive at the invention of claim 26?

Findings of Fact

1. Weitzel discloses "extracorporeal circuits for use in treating a body fluid … adapted to provide precise control of flow rate, temperature, and pressure through the circuit" (Weitzel, col. 1, ll. 51-54).

2. Weitzel discloses that the body fluid may be blood (*id.* at col. 4, ll. 40-42).

3. Weitzel discloses that the circuit comprises "an inlet for receiving a body fluid from a patient, a first pump, a first treatment device for processing the body fluid, a second pump, an outlet for returning processed body fluid to the patient and a shunt" (*id.* at col. 1, l. 65 to col. 2, l. 3).

4. Weitzel's circuit also includes a heat exchanger upstream of the treatment device (*id.* at col. 6, ll. 11-14).

5. Weitzel discloses that the "heat exchanger can be … a water bath at least partially surrounding any portion of the intake line" (*id.* at col. 6, ll. 19-21).

6. Polaschegg discloses an apparatus "for treating blood in an extracorporeal circuit for hemodialysis or hemofiltration and a method ... for withdrawing heat from blood in an extracorporeal circuit wherein blood is brought into contact along a membrane with a treatment solution which has been heated to a temperature" (*id.* at col. 3, ll. 5-11).

7. Polaschegg discloses that "the blood temperature, which correlates to the body temperature of the patient, is measured and compared with a predetermined value or a number of predetermined values, the temperature of the dialysis solution or the substitution solution being adjusted in accordance with the comparison result" (*id.* at col. 3, ll. 16-21).

8. Polaschegg's apparatus includes a temperature sensor 206 upstream of all blood treatment elements (*id.* at col. 7, l. 1; Fig. 1).

9. Polaschegg discloses that "[i]f only one temperature sensor 206 is disposed in the extracorporeal blood circuit the arterial blood temperature thereof is taken as reference temperature for the evaluating and control unit 208" (*id.* at col. 7, ll. 1-4).

10. Polaschegg discloses that "[i]f a temperature sensor 207 is additionally disposed in the venous blood path of the extracorporeal circuit the difference between the arterial temperature sensor 206 and venous temperature sensor 207 can also be selected as reference value" (*id.* at col. 7, ll. 4-8).

11. Polaschegg discloses that

> evaluating and control unit 208 receives the signals of the temperature sensors 206 and 207 and a signal from the blood pump 201 proportional to the blood pump flow. A signal line leads ... to the temperature regulating unit 106. ... The temperature of the dialysis solution or substitution solution is

> thereby raised or lowered to a temperature value calculated by the evaluating and control unit 208.

(*Id.* at col. 7, ll. 10-19.)

12. Polaschegg discloses that the "flowing past of the two media dialysis solution and blood plasma results in an exchange of heat taking place in the dialyzer. . . . The body temperature of the patient or his blood temperature is brought to a normal value or a value selected by the physician." (*Id.* at col. 7, ll. 22-24.)

13. Derek discloses a system that "is adapted to withdraw blood from a patient, combine the blood with a[n] oxygen-supersaturated physiologic fluid, and deliver the oxygen-enriched blood back to the patient" (Derek, col. 7, ll. 56-59).

14. Derek discloses that

> if it is desirable to control the temperature of the incoming blood in the draw tube 34 or the outgoing gas-enriched blood in the return tube 50, an appropriate device, such as a heat exchanger, may be operatively coupled to one or both of the tubes 34 and 50. Indeed, not only may the heat exchanger (not shown) be used to warm the fluid as it travels through the system 10, it may also be used to cool the fluid.

(*Id.* at col. 10, ll. 4-14).

15. Figure 2 of Derek is shown below:

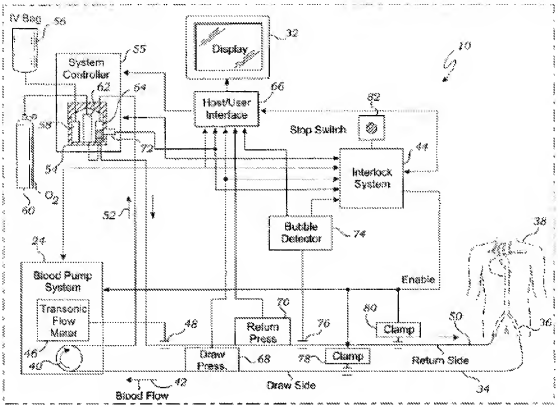

Figure 2 shows a block diagram of a system for producing gas-enriched fluid (*id.* at col. 5, ll. 30-33).

16. Derek discloses that the "blood is pumped through the draw tube 34 in the direction of the arrow 52 into an oxygenation device 54" (*id.* at col. 8, ll. 53-54) and the "oxygen-enriched blood is taken from the third chamber 64 of the oxygenation device 54 by the return tube 50" (*id.* at col. 9, ll. 13-15).

Principles of Law

"[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the answer depends on "whether the improvement is more than the predictable use of prior art elements according

to their established functions." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007).

The obviousness analysis "can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418.

Analysis

Claim 26 is directed to an extracorporeal blood treatment apparatus comprising a sensor in the access branch, upstream of all blood treatment elements, for measuring the temperature of blood leaving the patient and a temperature regulating device (heat exchanger) coupled to the return branch, downstream of all blood treatment elements, to regulate the temperature of the blood. Claim 26 also requires a control unit that is connected to the temperature regulating device and that controls the temperature of the fluid in the heat exchanger as a function of the blood temperature and a reference temperature.

Weitzel discloses an extracorporeal blood treatment device that includes a heat exchanger for regulating the temperature of blood entering the treatment component of the device. Polaschegg discloses a temperature sensor in the access branch of an extracorporeal blood treatment device. Polaschegg also discloses the desirability of adjusting the temperature of treated blood in the apparatus as a function of the temperature of the blood in the access branch or as a function of the difference between the temperature of the blood in the access and return branches. Derek discloses an extracorporeal blood treatment device with a heat exchanger on the return branch of the circuit.

In view of these disclosures, it would have been obvious to one of skill in the art to modify Weitzel's extracorporeal blood treatment apparatus to include a temperature sensor upstream of the treatment device, as disclosed by Polaschegg, and a temperature regulating device in the return branch, as disclosed by Derek. Polaschegg discloses monitoring blood temperature in the access branch and using the obtained temperature information to appropriately adjust the temperature of blood that is returned to the patient. One of skill in the art would have understood that a heat exchanger in the return branch, as disclosed by Derek, would also achieve the temperature regulation suggested in Polaschegg. Such a combination is no more than the predictable use of prior art elements according to their established functions.

Appellants argue that the cited references do not suggest a heat exchanger downstream of all blood treatment elements (Appeal Br. 17). Appellants argue the Examiner's reliance on Derek is misplaced because "the cited passage in Derek is unclear and Derek fails to provide details about the components present on return tube 50 or the structure of the tube itself," and thus Derek does not disclose a heat exchanger downstream of all blood treatment elements and directly before the blood is returned to the patient (*id.*).

This argument is not persuasive. Derek describes the heat exchanger as being located on either or both of the draw tube and the return tube (FF 14). Figure 2 shows the return tube 50 as being downstream of chambers 58, 62, and 64 of the blood treatment device. Thus, Derek reasonably

appears to suggest a heat exchanger that is downstream of all blood treatment elements and directly before the blood is returned to the patient.

Appellants also argue that the cited references do not disclose the claimed heat exchanger that regulates temperature as a function of the temperature of blood in the access branch and a reference temperature (Appeal Br. 17).

This argument is not persuasive. As discussed above, Polaschegg discloses the desirability of regulating temperature as a function of the temperature in the access branch (i.e., the first temperature) and a reference temperature (i.e., the temperature desired for blood returned to the patient; FF 12). Polaschegg, Derek, and Weitzel all disclose that the temperature of blood in the circuit can be regulated by a heat exchanger (FFs 5, 12, 14). As discussed above, Derek teaches locating the heat exchanger in the return branch. Thus, using a heat exchanger to regulate temperature in the return branch as a function of the blood temperature and a reference temperature is simply the use of prior art elements for their established functions.

With regard to claim 45, Appellants argue that the cited references do not disclose or suggest "the fluid temperature being regulated as a function of the first temperature and of the reference temperature, and the fluid temperature being kept equal to the reference temperature when the pump is not in operation" (Appeal Br. 19).

This argument is not persuasive. Polaschegg discloses that heat is exchanged between blood and dialysis solution, and that the temperature of the dialysis solution is adjusted based on, among other thing, the rate of flow through the blood pump. It would have been recognized by those of

ordinary skill in the art that when the blood is not flowing, it will remain in contact with the dialysis solution and the blood and dialysis solution will come to temperature equilibrium (i.e., the same temperature). Therefore, it would have been obvious to maintain the solution in a heat exchanger at the desired reference temperature at times when the pump is not operating (and therefore blood is not flowing).

CONCLUSIONS OF LAW

The evidence of record supports the Examiner's conclusions that (i) the cited references suggest a heat exchanger downstream of all blood treatment elements and directly before blood is returned to the patient that regulates the blood temperature as a function of temperature in the access branch and a reference temperature and (ii) that one of skill in the art would have been motivated to combine the cited references to arrive at the claimed invention.

SUMMARY

We affirm the rejection claims 26 and 28-50 under 35 U.S.C. § 103(a) as being obvious in view of Weitzel, Polaschegg, and Derek.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

lp

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON DC 20001-4413